UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

NICOLE CRESAP, *individually and as estate administrator for her deceased minor child* **KENNEDY HAYES,** *Plaintiff*, v. **ABBOTT LABORATORIES** and **ABBOTT LABORATORIES, INC.** *Defendants*.	
Complaint with Jury Demand	

NATURE OF ACTION

1. This action arises out of the injury of a premature infant, who was afflicted with a disease caused by cow's-milk-based infant formula and fortifier manufactured and sold by Defendant Abbott Laboratories, Inc.

2. Necrotizing enterocolitis ("NEC") is a deadly disease that largely affects low-birth-weight babies who are fed cow's-milk-based formula or products. Kennedy Hayes, an extremely prematurely born, low-birth-weight baby, was fed Similac® formula, Similac® "human milk fortifier," and Abbott Nutrition "liquid protein fortifier" and developed NEC as a result. Plaintiff Nicole Cresap files this complaint against Defendant for negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, and distribution, labeling, and/or sale of the products known as Similac® Special Care®

24 High Protein, Similac® Special Care® 30, Similac® Human Milk Fortifier, and Abbott Nutrition Liquid Protein Fortifier (referred to as "the Products").

THE PARTIES

3. Kennedy Jade Elizabeth Hayes ("Baby Kennedy") was born at Morristown Medical Center in Morristown, New Jersey on December 30, 2021. She developed NEC and died after being fed the Products. Baby Kennedy was a resident of New Jersey.

4. Nicole Cresap is the mother of Baby Kennedy. She brings this action individually and as estate administrator for Baby Kennedy. Ms. Cresap is a resident of New Jersey.

5. Defendant Abbott Laboratories is a corporation organized under the laws of the State of Illinois with its principal place of business in this jurisdiction. It is the parent company of its wholly owned subsidiary, Defendant Abbott Laboratories, Inc.

6. Defendant Abbott Laboratories, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business in this jurisdiction. Defendant Abbott Laboratories, Inc. is a wholly owned subsidiary of its parent company, Abbott Laboratories.

7. On information and belief, for all purposes relevant to this Complaint, Abbott Laboratories and Abbott Laboratories, Inc. functioned as one entity, so this Complaint will refer to both collectively as "Defendant" or "Abbott."

JURISDICTION

8. This Court has original jurisdiction under 28 U.S.C. § 1332(a) because Plaintiff and Defendant are citizens of different states and the matter in controversy, exclusive of interest and costs, exceeds $75,000.

9. This Court has personal jurisdiction over Defendant and venue is proper here because Defendant is a citizen of this State with its principal place of business in this jurisdiction. 28 U.S.C. §§ 1391(b).

FACTUAL BACKGROUND

The Science, The Products, The Marketing, and The Baby

The Science: Cow's-milk-based formulas significantly increase the risk of NEC in premature infants

10. According to the World Health Organization ("WHO"), babies born alive before 37 weeks of pregnancy are completed, like Baby Kennedy, are defined as "premature" or "preterm." The WHO estimates that approximately 15 million babies are born preterm every year, and that number is rising.

11. Optimal nutrition for preterm babies, especially those who have a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams), like Baby Kennedy (born at 712 grams), is important for the babies' survival.

12. The United States ranks tenth or higher in the list of countries with the highest number of preterm births.

13. The medical and scientific community traditionally believed that infant formulas based on cow's milk were beneficial for the growth of premature, low-birth-weight babies. But for decades, medical and scientific research have established that

feeding premature infants cow's-milk-based formulas (like the Products) can cause NEC—which may require surgery or cause death—in preterm, low-birth-weight infants, and many other health complications and long-term risks.

14. Despite having knowledge of these medical and scientific studies and advances, Defendant did nothing to change the design or formulation of its cow's-milk-based formulas and fortifiers. Likewise, Defendant did nothing to change its cow's-milk-based products' packaging, guidelines, instructions, and/or warnings.

15. Feasible alternatives to cow's-milk-based products that do not substantially increase the risk of NEC for premature infants exist, including formulas and fortifiers derived from human milk and amino acids. Defendant, however, continues to promote and sell cow's-milk-based products for feeding to premature infants.

16. Medical science and research establish the strong causal relationship between cow's-milk-based products and NEC and death in premature infants.

17. As early as 1990, a prospective multicentre study on 926 preterm infants found that NEC was six–ten times more common in exclusively formula-fed babies than in babies fed breast milk alone, and three times more common than in those who received formula plus breast milk. Among babies born at more than 30 weeks' gestation, confirmed NEC was rare in those whose diet included breast milk; it was 20 times more common in those fed formula only. Lucas T. Cole, *Breast Milk and Neonatal Necrotising Enterocolitis,* 336 Lancet 1519–23 (1990).

18. Premature infants have immature gastrointestinal systems, especially as compared to the gastrointestinal systems of term infants. The specific physiology of

the preterm gastrointestinal system makes premature babies vulnerable to NEC: "The preterm gut is characterized by reduced peristalsis, a thin mucous layer, reduced tight junctions, increased enterocyte apoptosis, and impaired enterocyte regeneration. Decreased structural integrity and functionality of the gut result in poor digestion and absorption of energy, protein, and other nutrients necessary for growth, the development of organs, and immunoprotection." Jocelyn Shulhan et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm and the Impact of Different Types of Enteral Nutrition Products*, 8 Adv. Nutr. 80–91 (2017).

19. Preterm infants' immune systems are also significantly different than those of term infants, which compounds their susceptibility to NEC when fed unsafe products: "[T]here are distinct differences between term and preterm infants in regard to the expression of immune cells and signaling pathways. A preterm immune system cannot readily detect pathogens and protect against infections due to multiple associated factors such as 1) the decreased production of IgA, IgM, IgG, and defensins; 2) changes in the expression of toll-like receptors (TLRs), especially TLR4 and TLR9, which are involved in pathogen recognition and the activation of the innate immune system; and 3) upregulation of proinflammatory TLRs and/or proinflammatory cytokines…. The culmination of these factors increases a preterm infant's vulnerability to infections and disease, particularly NEC." *Id*.

20. A study published in 2010 established that when premature babies were fed an exclusive diet of mother's milk, donor milk, and human milk fortifier, these babies were 90% less likely to develop surgical NEC. S. Sullivan et al., *An Exclusively*

Human Milk-Based Diet Is Associated with a Lower Rate of Necrotising Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products, 156 Journal of Pediatrics, 562–67 (2010).

21. In 2011, the Surgeon General published a report titled The Surgeon General's Call to Action to Support Breastfeeding, warning that, "[f]or vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis (NEC)." U.S. Dept. of Health & Human Services, *The Surgeon General's Call to Action to Support Breastfeeding*, Washington, D.C., Office of the Surgeon General; 2011, p.1. This same report stated that premature infants who are not breastfed are 138% more likely to develop NEC. *Id*., Table 1, p. 2.

22. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human-milk diet because of the risk of NEC associated with the consumption of cow's-milk-based formula. The Academy stated that, "[t]he potent benefits of human milk are such that all preterm infants should receive human milk. . . If the mother's own milk is unavailable . . . pasteurized donor milk should be used." Margreete Johnston et al., *Breastfeeding and the Use of Human Milk*, 129 Pediatrics 827–41 (2012).

23. A study published in 2013 showed that all 104 premature infants participating in the study receiving an exclusive human-milk-based diet exceeded targeted growth standards and length and HC gain (weight and head circumference). The authors concluded that "this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based

diet." Amy B. Hair et al., *Human Milk Feeding Supports Adequate Growth in Infants ≤ 1250 Grams Birth Weight*, 6 BMC Research Notes 459 (2013).

24. Another study published in 2013 reported: "This is the first randomized trial in EP [extremely premature] infants of exclusive HM [human milk] vs. PR [preterm formula]. The significantly shorter duration of TPN [total parenteral nutrition] and lower rate of surgical NEC support major changes in the strategy to nourish EP infants in the NICU [neonatal intensive care unit]." E.A. Cristofalo et al., *Randomized trial of Exclusive Human Milk versus Preterm formula*, 163 J. Pediatrics 1592–95 (2013).

25. In another study published in 2014, it was reported: "Necrotizing enterocolitis (NEC) is a devastating disease of premature infants and is associated with significant morbidity and mortality. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good et al., *Evidence-Based Feeding Strategies Before and After Development of Necrotizing Enterocolitis*, 10 Expert Rev. Clin. Immunol. 875–84 (2014).

26. That same study reported: "Necrotizing enterocolitis (NEC) is the most frequent and lethal gastrointestinal disorder affecting preterm infants, and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. NEC affects 7–12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. The typical patient who develops NEC is a premature infant who

displays a rapid progression from mild feeding intolerance to systemic sepsis, and up to 30% of infants will die from this disease." "A wide variety of feeding practices exist on how to feed premature infants in the hopes of preventing necrotizing enterocolitis. There have been several meta-analysis [*sic*] reviewing the timing of administration and rate of advancement of enteral feedings in the premature infant as reviewed above, but there is no consensus on the precise feeding strategy to prevent this disease. The exclusive use of human breast milk is recommended for all premature infants and is associated with a significant decrease in the incidence of NEC." *Id*.

27. In yet another study published in 2014, scientists reported: "An exclusive human milk diet, devoid of CM [cow's-milk]-containing products was associated with lower mortality and morbidity in EP [extremely premature] infants without compromising growth and should be considered as an approach to nutritional care of these infants." Steven Abrams et al., *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, 9 Breastfeeding Medicine 281–285 (2014).

28. A 2016 study supported previous findings that an exclusive human-milk diet in extremely premature infants dramatically decreased the incidence of both medical and surgical NEC. This was the first large-scale study to compare rates of NEC after a feeding protocol implementation at multiple institutions with multiple years of follow-up using an exclusive human-milk diet. The authors concluded that "the use of an exclusive HUM [human-milk] diet is associated with significant benefits for extremely premature infants" and "while evaluating the benefits of using an exclusive

HUM-based protocol, it appears that there were no feeding-related adverse outcomes." Amy B. Hair et al., *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet*, 11 Breastfeeding Medicine 70–74 (2016).

29. An article published in 2017 reported: "In summary, HM has been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC. Two RCTs on preterm infants weighing between 500 and 1250g at birth compared the effect of bovine milk-based preterm infant formula to MOM [mother's own milk] or DHM [donor human milk] on the incidence of NEC. Both trials found that an exclusive HM diet results in a lower incidence of NEC." Jocelyn Shulhan et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm and the Impact of Different Types of Enteral Nutrition Products*, 8 Adv. Nutr. 80–91 (2017).

30. Another study published in 2017 reported: "Human milk is the preferred diet for preterm infants as it protects against a multitude of NICU challenges, specifically necrotizing enterocolitis … Preterm infants are susceptible to NEC due to the immaturity of their gastrointestinal and immune systems. An exclusive human milk diet compensates for these immature systems in many ways such as lowering gastric pH, enhancing intestinal motility, decreasing epithelial permeability, and altering the composition of bacterial flora. Ideally, preterm infants should be fed human milk and avoid bovine protein. A diet consisting of human milk-based human milk fortifier is one way to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a human milk diet." Diana Maffei et

al., *Human Milk is the Feeding Strategy to Prevent Necrotizing Enterocolitis!* 41 Semin Perinatal. 36–40 (2017)

31. A 2020 review explained: "Due to the lack of effective treatments for NEC, research focus has shifted to testing strategies for the prevention of NEC, specifically early exposure to colostrum and mother's own milk ….Colostrum, the first milk produced by mothers in the days after birth, has been shown to contain high concentrations of beneficial immune mediators that provide bacterial and anti-inflammatory protection, and stimulate the development of the GI tract… Human breast milk contains many factors thought to help prevent NEC including nitrate/nitrite antioxidant factors, L-arginine, human milk oligosaccharides and prebiotics, secretory IgA, platelet-activating factor acetylhydrolase, lactoferrin, and growth factors." Alissa L. Meister et al., *Necrotizing Enterocolitis: It's Not All in the Gut*, 245 Experimental Biology and Medicine 85–95 (2020).

32. Another 2020 review stated: "Human milk is the only modifiable risk factor that has been consistently shown to protect against the development of NEC." Jocelyn Ou et al., *Nutrition in Necrotizing Enterocolitis and Following Intestinal Resection*, 12 Nutrients 520 (2020). "The specific mechanisms by which breast milk is protective continue to be studied. However, several non-nutrient components have been found to contribute to the immune functions of the gastrointestinal tract and augment mucosal integrity. These include secretory IgA, growth hormones (epidermal growth factor, insulin, and insulin-like growth factor), polyunsaturated fatty acids, and oligosaccharides. A 2019 study found that not only is an infant's IgA largely derived

from maternal milk in the first month of life, but also that infants with NEC have larger proportions of IgA-unbound bacteria compared to age-matched controls." *Id*. Scientific studies also establish that necrotizing enterocolitis carries significant risks for long-term complications among surviving infants. NEC requiring surgical treatment is causally associated with increased rates of neurodevelopmental delays, failure to thrive, intestinal failure, short-bowel syndrome, feeding difficulties, intestinal strictures, and intestinal adhesions with small-bowel obstruction. Catalina Bazacliu et al., *Necrotizing Enterocolitis: Long Term Complications*, 15 Current Pediatric Reviews 115–24 (2019).

33. In summary, medical studies (including studies published before Baby Kennedy was born) clearly established that: (1) NEC causes serious short-term and long-term medical problems for infants who develop the disease; (2) cow's-milk-based infant formula substantially increases the risk of low birth weight/premature infants developing NEC and (3) growth and nutritional benchmarks can be reached or exceeded in premature, low-birth-weight infants who are fed an exclusive diet of human milk (mother's milk, donor milk, or a human-milk-derived formula or fortifier such as Prolacta).

The Products:
Defendant's cow's-milk-based formulas and fortifiers

34. Defendant's Similac® Special Care® 24 High Protein is a cow's-milk-based product.

35. Defendant's Similac® Special Care® 30 High Protein is a cow's-milk-based product.

36. Defendant's Similac® Human Milk Fortifier (whether in the form of a powder or a concentrated liquid) is a cow's-milk-based product.

37. Defendant's Abbott Nutrition Liquid Protein Fortifier is a cow's-milk-based product.

38. Feeding cow's-milk-based products to a premature infant significantly increases the risk that the infant will develop NEC, sustain devastating injuries, require surgery, and/or die.

39. Defendant's cow's-milk-based Similac® and Abbott Nutrition products are dangerous to premature infants because the products significantly increase the risk that these infants will develop NEC, sustain devastating injuries, require surgery, and/or die.

40. Despite knowing that these products significantly increase the risk of NEC, devastating injuries, surgical intervention, and/or death for premature infants, Defendant deliberately choose not to provide a specific warning of these risks.

41. Defendant failed to properly warn consumers that its cow's-milk-based products significantly increase the risk that a preterm infant will develop NEC, sustain devastating injuries, require surgery, and/or die.

42. Before Baby Kennedy developed NEC, Defendant knew or should have known that its cow's-milk-based products were not safe to feed to premature infants. Yet Defendant took no steps to prevent such use among this vulnerable infant population.

43. Before Baby Kennedy developed NEC, Defendant did foresee or should have foreseen that its products would be used as they were in this case—for feeding

premature infants—and knew or should have known that such use would significantly increase the risk of premature infants developing NEC. Yet Defendant took no steps to prevent such use among this vulnerable infant population.

44. Defendant's cow's-milk-based products were not safe to be used as they were used in this case, and Defendant knew or should have known they were unsafe, yet Defendant failed to properly instruct and/or warn the FDA, NICUs, hospitals, doctors, and parents that these products were unsafe.

45. Defendant's cow's-milk-based products were not safe to be used as they were used in this case, and Defendant knew or should have known they were unsafe. Yet Defendant failed to provide detailed instructions or guidelines on when, whether, and how its products would be safe to use.

The Marketing:
Defendant's misleading marketing of cow's-milk-based Similac® formulas

46. Notwithstanding strong medical evidence establishing the extreme dangers that cow's-milk-based products pose for premature infants, Defendant has marketed its cow's-milk-based products as an equally safe alternative to breast milk for premature infants.

47. Defendant has promoted its products as not only safe but ***necessary*** for the growth and development of premature infants, when, in fact, its products pose a known and substantial risk to these babies and are not necessary for their growth and development.

48. Defendant's practice of trying to get mothers of both preterm and term infants to choose formula over breast milk—without accounting for the different

physiological needs and NEC risks between these infant populations—goes back decades. Defendant has promoted its cow's-milk-based products as healthier, necessary for adequate nutrition, supported by "science," and the choice for the modern, sophisticated mother. Indeed, Defendant's advertising has attempted to portray breastfeeding as inferior to and less sophisticated than formula feeding.

49. Defendant's marketing for cow's-milk-based Similac® products (which are available for purchase by the public) and Abbott Nutrition products (which are available for purchase by medical providers) failed to warn consumers about the crucial physiological differences between term and preterm infants, including preterm infants' far greater risk of developing NEC as a result of being fed cow's-milk-based formulas.

50. Defendant's across-the-board marketing to parents of all infants begins early. Defendant sends marketing materials and formula samples to expectant mothers. Defendant routinely offers free cow's-milk-based formula and other goodies in baskets given to mothers of both term and preterm infants after they give birth in hospitals and medical clinics. Defendant promotes its products to parents of newborns in medical facilities to create brand loyalty and the appearance of "medical blessing" so that mothers continue to feed their babies formula after the leave the hospital, at great expense to the parents and great risk to premature infants.

51. The WHO and the United Nation's International Children's Emergency Fund ("UNICEF") held a meeting more than two decades ago to address the international marketing of breast-milk substitutes. The WHO Director concluded the meeting with

the following statement: "In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement." Baumslag & Michels, *Milk, Money, and Madness: the Culture and Politics of Breastfeeding* (1995), p. 161.

52. For years, the international health community has recognized the abuse and dangers of infant-formula marketing. In 1981, the World Health Assembly (WHO's decision-making body) developed an International Code of Marketing of Breast-milk Substitutes ("the Code"), which recommended that companies be required to acknowledge the superiority of breast milk and condemned any advertising or promotion of breast-milk substitutes to the general public. More than 40 years ago, the Code specifically condemned such advertising: "There should be no advertising or other form of promotion to the general public …" International Code of Marketing of Breast Milk Substitutes. WHO, Geneva, Art. 5, § 1, 16–20 (1981).

53. Defendant has acknowledged the Code. "We support, educate[,] and encourage mothers to breast-feed for as long as possible, including, where possible, exclusive breast-feeding during the first six months of life and continued breast-feeding up to and beyond two years of age. . . We acknowledge the importance of the World Health Organization's 1981 International Code of Marketing of Breast-[m]ilk Substitutes (the 'WHO Code') and subsequent World Health Assembly (WHA) resolutions. We respect the aim and principles of the WHO Code to contribute to the provision of safe and adequate nutrition for infants, by: a) the protection and promotion of breast-feeding; and b) ensuring the proper use of Breast-milk Substitutes, when these are

necessary, on the basis of adequate information and through appropriate marketing and distribution. We acknowledge that, independently of any other measures taken by governments to implement the WHO Code, we are responsible for monitoring our marketing practices according to the principles and aims of the Code, and for taking steps to ensure that our conduct at every level in this regard conforms to this Infant Formula Marketing Policy and local law in the countries where we operate." Abbott Laboratories, Inc., *Abbott Policy on the Marketing of Infant Formula, Version 2,* WWW.ABBOTT.COM, p. 3–4, https://dam.abbott.com/en-us/documents/pdfs/transparency/Abbott_Policy_on_the_Marketing_of_Infant_Formula.pdf (last visited Apr. 14, 2022).

54. Despite this assurance and warranty contained in its Policy, Defendant has systematically violated the Code's most important provision: "There should be no advertising or other form of promotion to the general public…"

55. Notwithstanding the Code, and Defendant express commitment to the Code, advertising of infant formula has remained pervasive and widespread in the United States. Defendant aggressively markets and continues to advertise directly to new parents by suggesting that by buying the Products, they will benefit their newborns and give them the very best chance of survival. The pervasive marketing involved, ostensibly prohibited by the Code, has impacted the perceptions of synthetic non-human-milk-derived substitutes, such as a formula and fortifier, in such a way that it lessens the likelihood that a parent of a baby receiving this food in the NICU will

ask questions, query about alternatives, or object to its ingestion. In short, Defendant has systematically violated the Code's central provision.

56. Similac® was deceptive from its very inception. Similac®'s name (i.e., *simi*lar to *lac*tation) is deceptive. Beginning with the selection of its brand name, Defendant has continued to perpetuate the deception that its products are on par with or similar to human milk. This marketing has altered the perceptions of parents and directly contradicts the medicine and the science.

57. Defendant aggressively markets and continues to advertise directly to parents of both term and preterm infants by suggesting that buying the Products gives their newborns the very best chance to survive and thrive.

58. Defendant's pervasive marketing, ostensibly prohibited by the Code, has affected the perceptions of synthetic non-human-milk-derived substitutes, such as cow's-milk-based formula and fortifier, to make parents believe it is safe for all infants.

59. As the WHO and UNICEF reported in February 2022—40 years after the Code was promulgated: "formula milk marketing still represents one of the most underappreciated risks to infants' and children's health." World Health Organization, *How the Marketing of Formula Milk Influences Our Decisions on Infant Feeding* (2022), available at https://www.who.int/publications/i/item/9789240044609 (last visited Apr. 12, 2022). This "distortion of objective information and the misuse of science negatively impacts on access to accurate and impartial information—an essential human right as stated in the Convention on the Rights of the Child." *Id.*

60. A 2020 review concluded that, notwithstanding the Code, which "aims to shield parents from unfair commercial pressures," formula marketing "remains widespread because some countries (e.g., the USA) have not adopted the Code, and elsewhere industry has developed follow-on and specialist milks by which they promote formula by proxy." Gerard Hastings et al., *Selling Second Best: How Infant Formula Marketing Works*, 16 Globalization and Health 77–88 (2020).

61. The marketing techniques deployed by Defendant and other formula companies have become more pervasive and insidious in the age of social media: "The campaigns use emotional appeals to reach out to and build relationships with parents and especially mothers…The advent of social media has made it easier to pose as the friend and supporter of parents; it is also providing companies a rich stream of personal data with which they hone and target their campaigns." *Id*.

62. Defendant's and other formula companies' efforts to portray themselves as benevolent sources of emotional support for new parents seek to conceal their profit motives: "The formula industry is dominated by a small number of extremely powerful multinational corporations with the resources to buy the best global marketing expertise. Like all corporations[,] they are governed by the fiduciary imperative which puts the pursuit of profits ahead of all other concerns. The mix of fiscal power, sophisticated marketing, and single-mindedness is causing great harm to public health." *Id*.

63. Defendant's marketing makes it less likely that the parents of a premature infant receiving cow's-milk-based formula or fortifier in the NICU will ask questions

about the products' safety, ask for a non-cow's-milk-based alternative (like human donor milk or human-milk-based products), or object to their babies ingesting such products. In short, Defendant has systematically violated the Code's central provision.

64. One study reports that "[s]ince the late 19th Century, infant formula manufacturers have encouraged mother to substitute formula for breast milk." Kenneth Rosenberg et al., *Marketing Infant Formula Through Hospitals: the Impact of Commercial Hospital Discharge Packs on Breastfeeding*, 98 Am. J. Public Health 290–95 (2008). The same study has also found that manufacturers have repeatedly used their relationships with hospitals and the discharge process to encourage mothers of both term and preterm infants to substitute formula for breast milk even after they leave the hospital. *Id.*

65. This kind of marketing practice undermines the doctor-patient relationship and reduces a parent's capacity to make informed decisions regarding an infant's care.

66. Indeed, most hospitals in the U.S. distribute "commercial discharge bags packaged as smart diaper bags containing various coupons, advertisements, baby products, and infant formula samples." Yeon Bai et al., *Alternative Hospital Gift Bags and Breastfeeding Exclusivity*, 2013 ISRN Nutrition, article ID 560810 1–7 (2013). These commercial gift bags send confusing signals to breastfeeding mothers about the feasibility of continued breastfeeding and have been shown to negatively impact breastfeeding rates. *Id.* at 5. But the practice continues because it is a very effective

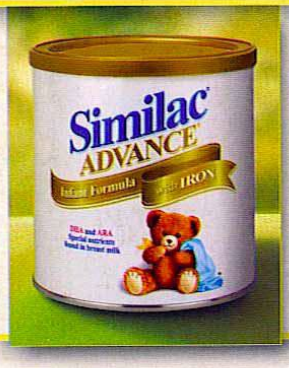
way to solicit customers, including the parents of preterm infants, who are encompassed within the company's across-the-board marketing strategy.

67. Defendant routinely compares its Similac® products with human breast milk and attempts to create an equivalency. For example, an advertisement for Similac® Advance published on the back cover of American Baby Magazine in April 2004 made repeated references and comparisons to breast milk, and indeed the one-page ad uses the phrases "like breastmilk" six times:

Similac® Advance® can help develop both your baby's immune system and brain like breast milk.

(Kisses, hugs, and silly songs are up to you.)

Breastfeeding is recommended for its many benefits. If you choose to feed formula, ask your doctor about Similac Advance.



Only Similac Advance with DHA and ARA has both*:

- A patented blend of special breast milk nutrients called nucleotides, which has been clinically shown to help support the development of a baby's immune system like breast milk.
  The clinical study showed immune cell development like breast milk. Whether this development provides immune protection like breast milk has not been shown. Breast milk also contains antibodies not found in infant formulas that are important for a baby's immune protection.
- Published long-term clinical research showing brain development like breast milk.*

So much like breast milk in so many ways.

*Among formulas with DHA and ARA; infants studied at 12 and 39 months of age. ©2004 Abbott Laboratories.
www.SimilacAdvance.com

See also Angela Broussard Hyderkhan, *Mammary Malfunction: A Comparison of Breastfeeding and Bottle Feeding Product Ads with Magazine Article Content*, LSU Master's Thesis (2005).

68. The pervasive exposure of mothers to media, advertising, and promotion equating human milk to breastmilk has the generalized impact of: (a) reducing lactation; (b) causing mothers to believe that formula is comparable to breast milk; and (c) reducing the capacity for informed consent and informed decision-making. Through long-term exposure to Abbott's advertising, Baby Kennedy's mother had been conditioned and was caused to believe that Similac® products (and, by extension, Abbott Nutrition products sold only to hospitals like Liquid Protein Fortifiers) are suitable alternatives to breastmilk and necessary supplements for low-birth-weight infants.

69. In addition to perpetuating the myth that Similac® is "like breast milk," Abbott has also deceived the public into believing that physicians believe Similac® is an ideal choice for babies.

70. Beginning in 1989, Abbott began using claims in its advertising that Similac® was the "first choice of more physicians."

71. Although the claim did not expressly compare itself to breast milk, a plain interpretation of this claim that Similac® is physicians' "first choice" naturally implies that it is superior to breastfeeding.

72. Beginning in 1995, Defendant began a heavy marketing campaign that featured "first choice of doctors" on all its infant formula product labels.

73. A marketing report issued by Defendant in March, 1998 summarized consumer reactions to several informational advertising pamphlets on Similac®. The one stressing the "first choice of doctors" claim scored highest in terms of consumers' likelihood of purchase. The report concluded: "Doctor recommendations and the 'science' behind the formula appeared to drive purchase interest for this concept, as well as the other concepts tested," and use of similar pieces emphasizing the claim was "highly recommended."

74. Defendant's efforts to expose parents of both term and preterm infants to media, advertising, and promotion within hospitals and doctors' offices equating human milk to breastmilk has the generalized impact of:

a. causing parents to believe that cow's-milk-based formula is equally as safe for preterm infants as it is for term infants;

b. reducing lactation efforts and lactation;

c. causing mothers to believe that formula is equivalent to breast milk in terms of nutrition, digestibility, and health risks; and

d. reducing infants' parents' capacity for informed consent and informed decision-making.

75. Through long-term exposure to Defendant's advertising, Baby Kennedy's mother, Ms. Cresap, had been conditioned to believe that Similac® products are suitable alternatives to breastmilk and necessary supplements for premature and low-birth-weight infants.

76. The scope of Defendant's and other formula companies' marketing efforts is vast. One study estimates that formula manufacturers spent $4.48 billion on marketing and promotion in 2014. Philip Baker et al., *Global Trends and Patterns of*

Commercial Milk-based Formula Sales: Is an Unprecedented Infant and Young Child Feeding Transition Underway? 19 Public Health Nutrition 2540–50 (2016).

77. Moreover, the data indicate that these marketing efforts are successful at achieving brand-name recognition among consumers. One study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would prescribe those brands. R. Stephen Parker et al., *Ethical Considerations in the Use of Direct-to-consumer Advertising and Pharmaceutical Promotions: The Impact on Pharmaceutical Sales and Physicians,* 48 J. of Business Ethics 279–90. (2003).

78. Despite knowing that feeding premature infants cow's-milk-based formulas significantly increases the risk of NEC and that breastfeeding significantly reduces the risk of NEC, Defendant persists with marketing that is part of a broader industry-wide campaign to convince mothers that breastfeeding (instead of or in addition to formula feeding) is not feasible. The contradictory messages women receive from images, articles, and advertising in doctors' offices, hospitals, and popular magazines imply that breastfeeding is unnecessary and difficult if not impossible to achieve. *See* Bernice L. Hausman, *Rational Management: Medical Authority and Ideological Conflict in Ruth Lawrence's Breastfeeding: A Guide for the Medical Profession*. 9 Technical Communication Quarterly 271–89 (2000).

79. One study found that exposure to infant feeding information through media advertising has a negative effect on breastfeeding initiation. Merewood et al., *Exposure to Infant Feeding Information in the Media During Pregnancy is Associated*

with Feeding Decisions Postpartum, Paper presented at American Public Health Association 138th Annual Meeting & Exposition, Washington, D.C. (Nov. 2010).

80. In a study on infant feeding advertisements in 87 issues of Parents magazine, a popular parenting magazine, from the years 1971 through 1999, content analysis showed that when the frequency of infant formula advertisements increased, the percentage change in breastfeeding rates reported the next year generally tended to decrease. Jamie Stang et al., *Health Statements Made in Infant Formula Advertisements in Pregnancy and Early Parenting Magazines: A Content Analysis*, 2 Infant Child Adolesc. Nutr.16–25 (2010).[1]

81. The 2010 Stang study also found that infant-formula-company websites, printed materials, coupons, samples, toll-free infant-feeding-information lines, and labels may mislead consumers into purchasing a product that appears equivalent or superior to human milk for all infant populations. This may induce reliance on a biased source for infant-feeding guidance. *Id.*

82. Defendant has developed an advertisement campaign that attempts to create and capitalize upon a perception of "mommy wars." One advertisement that received significant attention—titled *The Mother 'Hood*—depicts a "war" where breastfeeding and formula-feeding moms are about to fight one another on a playground, but come together in the end to save a baby whose stroller rolls down a hill while the parents are preparing to rumble. The ad is effective because it is manipulative. In the ad, a formula-feeding mom proclaims: "Oh look, the breast police have arrived" as three

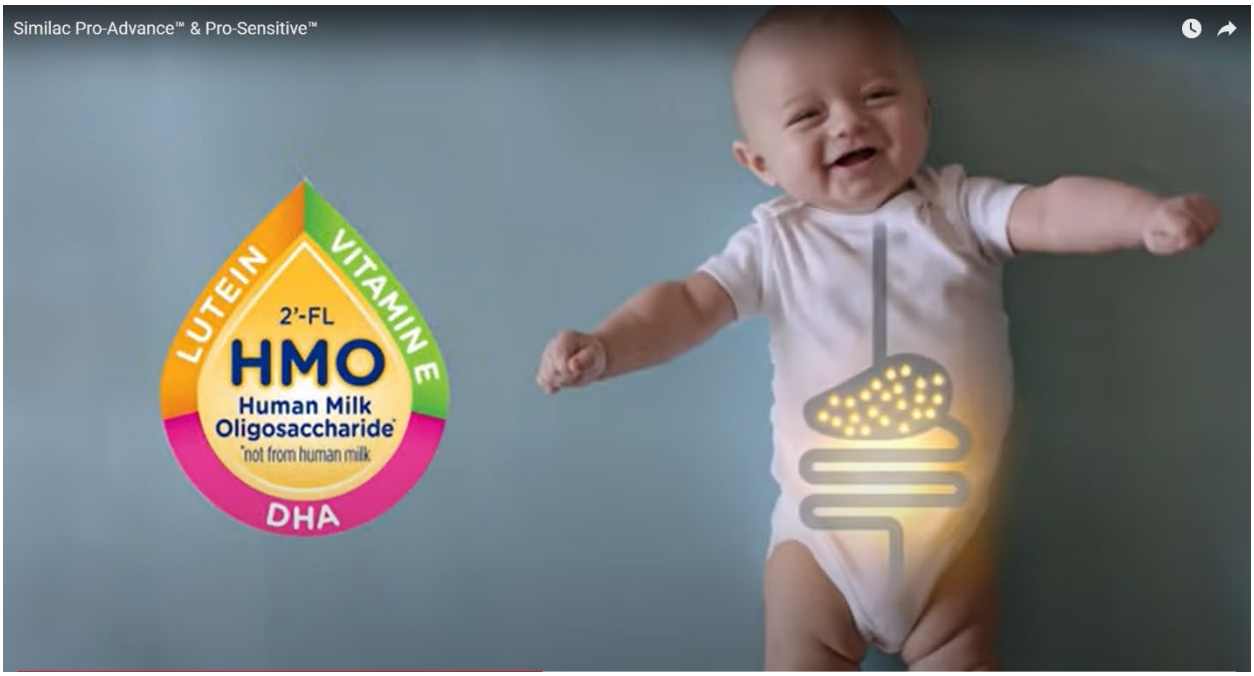
[1] *See also* Angela Broussard Hyderkhan, *Mammary Malfunction: A Comparison of Breastfeeding and Bottle Feeding Product Ads with Magazine Article Content*, LSU Master's Thesis (2005).

breastfeeding moms arrive. The breastfeeding moms are portrayed as arrogant and disdainful of the bottlefeeders. One breastfeeding mom proclaims condescendingly, "100% breast fed — straight from the source," another grasps her breast in a profane manner, and a third exclaims, "looks like some moms are too lazy to breastfeed." The negative portrayal of the breastfeeding moms casts them as mean, judgmental, and nasty while portraying the bottle-feeding moms as nurturing victims. https://www.youtube.com/watch?v=JUbGHeZCxe4 (last visited Apr. 14, 2022).

83. Another advertisement in Abbott's #EndMommyWars campaign—titled *The Judgment Stops Here*—is a powerful and moving documentary-styled ad showing mothers coming together, putting aside judgment of each others' choices. But the ad is manipulative, deceptive, and violative of the Code and Abbott's own marking policy in that it puts breast milk and formula on equal footing and attempts to chastise any judgment that might be cast in favor of what is clear scientific truth. In other words, the ad attempts to insulate Similac® from criticism or judgment, when criticism is wholly appropriate from a scientific standpoint because breast milk is, in fact, superior to formula. https://www.facebook.com/Similac/videos/1126104447462943/ (last visited Apr. 14, 2022).

84. In an advertisement for a Similac® product, Defendant's ad states, "when you are ready to turn to infant formula, but you don't want to compromise, look to Pure Bliss by Similac®. It's modeled after breast milk . . . it's thoughtfully crafted nutrition." https://www.youtube.com/watch?v=kRaHiTMyYXs (last visited Apr. 14, 2022).

85. In an advertisement for a Similac® product, the ad states that the formula contains "2'-FL human milk oligosaccharide, a nourishing prebiotic like that found in breast milk." The ad further states that "Similac® supports babies' developing immune system in the gut" and uses the following image to illustrate the claim:



While the image includes the fine print "*not from human milk" that caveat is not included in the ad's audio, so anyone listening to—rather than reading—the ad would not be aware that this "Human Milk Oligosaccharide" is not, in fact, from human milk. *See* https://www.youtube.com/watch?v=OWuqDb1PoG0 (last visited Apr. 14, 2022).

86. Moreover, Defendant has also attempted to market its products specifically to *premature* infants, who are the infants at highest risk from the dangers of its products.

87. In 1978, Defendant began marketing Similac® 24 LBW specifically for premature infants, claiming that the product was "introduced to meet the special needs of premature infants."

88. In 1980, Defendant began marketing Similac® Special Care® claiming it was "the first low-birth-weight, premature infant formula with a composition designed to meet fetal accretion rates."

89. In 1988, Defendant introduced and marketed Similac® Special Care® With Iron claiming it was "the first iron-fortified formula for premature and low-birth-weight infants introduced in the US."

90. As of 2016, Defendant marketed and sold seven products specifically targeting premature, low-birth-weight infants: Liquid Protein Fortifier, Similac®, NeoSure®, Similac® Human Milk Fortifiers, Similac® Special Care® 20, Similac® Special Care® 24, Similac® Special Care® 24 High Protein, and Similac® Special Care® 30.

91. On information and belief, Abbott specifically targets parents of premature infants in its marketing. For example, a Google search "feeding preemies formula" revealed a paid advertisement on the first page for Similac® NeoSure®, with the heading "For Babies Born Prematurely." *See* https://prod7-similac-2015-com.abbottnutrition.com/baby-formula/similac-expert-care-NeoSure-premature (last visited Apr. 14, 2022). The web-based advertisement stated: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac® NeoSure®, a nutrient-enriched formula for babies who were born prematurely, and help support her development." The

advertisement further claimed that it is "pediatrician recommended" and "#1 brand fed in Hospitals" and "backed by science." The advertisement makes no reference to specialized needs preterm infants have for human breast milk, and makes no mention of the risks of developing NEC.

92. At all relevant times, Defendant has had a website "similac.com" where mothers can choose the formula the corporation recommends using its "Formula Finder." By clicking on "Resources & Tools," the user is directed to a page where the following appears in large print: "Formula Finder — Find the Best Feeding Option for Your Child." *See* https://www.similac.com/baby-tools-resources/best-milk-formula.html (last visited Apr. 14, 2022).

93. In smaller type, Defendant states: "We promise to offer products that give your child a strong start. Let's find the right option for your little one." The first question in the Formula Finder asks "How old is your child?" with response options of "Newborn to 12 months" and "Older than 12 months." *Id*.

94. If the mother selects the first option, she is prompted to answer the question: "Was your child born prematurely?" If the mother clicks "yes," the website directs her to a page located at https://similac.com/formula-finder/baby-formula/similac-expert-care-NeoSure-premature. (last visited Apr. 14, 2022).

95. Through this website, Abbott directs mothers of premature babies to use Similac® NeoSure®—a cow's-milk-based formula—as the "Best Feeding Option," specifically stating it is "enriched nutrition" for premature infants. By clicking on "Learn More," the user is taken to the "Product Description" that describes the

product as "complete nutrition for babies born prematurely." *See* https://www.similac.com/products/preemie-formula/NeoSure-powder/22-8oz-can-4pack.html (last visited Apr. 14, 2022). The "Product Description" further states: "This special blend has protein, calories, vitamins, and minerals, including calcium, to help your baby grow. Similac® NeoSure® is from the #1 infant formula brand for premature babies."

96. In the promotional website described in the preceding paragraph, there is no mention of the risk of necrotizing enterocolitis. There is no mention of breast milk or human-milk-derived products as the "Best Feeding Option." This promotional web page expressly and implicitly represents that its cow's-milk-based products are safe for use with premature infants and a better option than breast milk. This is false and misleading.

97. Another advertisement by Defendant states that "whether you choose to formula feed or, to supplement breast feeding with formula, you can be confident in the nourishment of Similac®." *See* https://www.similac.com/why-similac.html (last visited Apr. 14, 2022). The representation to parents that they can be "confident" in what they "choose" is in direct contradiction of the studies that indicate that cow's-milk-based formula is dangerous to premature infants. Accordingly, it is false and misleading.

98. Defendant deliberately gives mothers the impression that the milk they produce is not enough to provide what their baby needs. It invites preemie moms to "sign up for our Similac® NeoSure® Rewards program" and claims that "[a] formula

such as Similac® NeoSure® is specially made for premature babies. It's designed to support brain, eyes, muscle, and bone growth, as well as your baby's immune system." But Defendant does not acknowledge that a nursing mother's body specially designs breast milk every day to do exactly those things. Abbott also tells moms that "human milk fortifier" "enhances mom's milk with extra protein, vitamins, and minerals to support a preemie's high nutrition needs for growth and development," without acknowledging that mom's milk provides baby with safe and adequate nutrition and does not need fortification. See Bringing Your Preemie Home: Make a preterm infant nutrition plan, https://www.similac.com/baby-feeding/premature-development/bringing-preemie-home.html (last visited Apr. 14, 2022).

99. Defendant's website also has reviews from mothers whose premature infants were in the NICU, and they discuss how wonderful and safe the products are. There are no mother reviews discussing NEC and death. This is false and misleading, and is perpetuated by Abbott. Abbott has designed a plan to induce parents to continue to purchase the product after leaving the NICU, at great expense.

100. In 2011, CBS News reported that Defendant paid mom bloggers to give positive reviews of its Similac® app. *See* https://www.cbsnews.com/news/abbott-pays-bloggers-for-positive-reviews-of-its-similac-app/ (last visited Apr. 14, 2022). Abbott's Similac® app is a tool it uses to create and maintain brand loyalty and collect data on mothers and their babies.

101. Defendant promotes NeoSure® on its website and other mediums as a safe product, and one specifically needed by preemies for adequate growth.

https://www.similac.com/baby-feeding/premature-development/preemie-catchup-growth.html (last visited March 7, 2022). Under the heading "Specialized Nutrition for Your Preemie," Abbott advises parents that preemies have "higher nutrient needs than full-term newborns" and "need tailored nutrition." Abbott advises mothers that a "preterm baby's nutrient needs are greater than what breast milk alone can provide." This is inaccurate and leads mothers to believe that their breast milk is insufficient for all premature infants.

102. The following is a true and accurate image of an Abbott ad targeting parents of premature infants:

Preterm nutrition is a story of specialization

Since preterm babies start smaller, their "catch-up growth" will have to be faster than usual for the baby to become the same size as a full-term baby.

Babies born prematurely have specific nutritional needs throughout the first year as their bodies work hard to grow and develop. The right nutrition for premature babies helps them grow in ways you can see, such as weight, length, and head size. Nutrition is also vital for growth you can't see.

Whether you choose to breastfeed or use baby formula, after leaving the hospital, most preemies will benefit from nutritional supplementation or a specialized formula with nutrients that support brain, muscle, bone, and organ growth, and development of a strong immune system.

Similac® NeoSure® is clinically shown to help with catch-up growth. It supports excellent growth during baby's first year, providing increased protein, energy, vitamins, and minerals compared to term infant formula. This means extra calories for growth, as well as calcium and phosphorus for baby's growing bones.

The fat blend in Similac NeoSure is 25% medium-chain triglycerides, an easily digested and well-absorbed fat source.

Similac NeoSure supports better gains in weight, length, and head circumference when compared to standard infant formula.

Read more about the benefits of Similac NeoSure and our **NEW value-size can.** Learn more

103. This same web page contains a video, promoting the necessity of formula as a means to achieve adequate growth in premature infants ("to help her catch up on the inside and the outside"). The page further claims that Similac® NeoSure is the "MOST EXTENSIVELY STUDIED PRETERM FORMULA" and "has been shown to promote growth and developmental outcomes of preemies when fed for the first full year." The video concludes by inviting parents to "count on the promise of Similac®." *See* https://similac.com/baby-formula/similac-expert-care-NeoSure-premature (last visited Apr. 14, 2022).

104. Recognizing a shift in the medical community towards an exclusive human-milk-based diet for premature infants, Defendant began developing a product called "Similac® Human Milk Fortifier." The name itself is misleading in that it suggests that the product is derived from human milk. But it is a cow's-milk-based product that contains no human milk. Canvasser, et al., *Parent and Provider Perspectives on the Imprecise Label of "Human Milk Fortifier" in the NICU*, Nutrients 2020, 12, 720.

105. Ms. Cresap did not know that Similac® Human Milk Fortifier was derived from cow's milk. The product's name is misleading and causes consumers to believe it is a human-milk-derived product.

106. Defendant's statements as set forth above ignore the Code, the American Academy of Pediatrics, and the numerous studies demonstrating the nutritional and immunological superiority of breast milk. Defendant's efforts to create a false equivalency between its products and breast milk are particularly dangerous for

premature infants, who are most at risk for developing NEC as a result of consuming Defendant's cow's-milk-based products.

107. Defendant's successful efforts to reduce breastfeeding rates in favor of cow's-milk-based formula feeding—thereby increasing its "share of stomach"—encompass mothers of premature infants, causing these babies to have an increased chance of NEC.

108. Defendant has designed and implemented a systemic, powerful, and misleading marketing campaign to deceive parents to believe that: (1) cow's-milk-based formula and fortifiers are safe for all babies; (2) cow's-milk-based products are equal or superior to breastmilk for all infant populations; and (3) physicians consider its cow's-milk-based products the best choice for every baby.

Defendant's specific marketing to premature babies' caregivers

109. In addition to including parents of premature infants within its general marketing claims regarding the safety of cow's-milk-based formula products as detailed above, Defendant has also specifically marketed cow's-milk-based formulas, including the Products, for feeding to premature infants.

110. Although Defendant knows and has known that cow's-milk-based formulas cause a significantly increased risk of NEC in premature infants, Defendant has continued to market and sell cow's-milk-based formulas for premature babies.

Defendant's inadequate warnings

111. Defendant's aggressive marketing campaign is designed to make parents believe that Defendant's products are safe and necessary for the growth of premature infants, despite decades of research that establish the fact that cow's-milk-based

products significantly increase the risk that a premature infant will develop NEC, require surgery, or die.

112. Defendant provides the following warnings for its product Similac® Special Care® 24 High Protein formula:

> Safety Precautions
>
> Very-low-birthweight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously.
>
> Tolerance to enteral feedings should be confirmed by initially offering small volumes of formula followed by cautious progression to higher caloric feedings.
>
> Spitting up, abdominal distension, abnormal stools or stool patterns, excessive gastric residuals, or other signs of intestinal dysfunction have been associated with enteral feeding before the intestinal tract is ready to accommodate the regimen. At first signs of these problems, enteral feeding should be slowed or discontinued.
>
> Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb) or as directed by a physician.
>
> **Never use a microwave oven to warm formula**. Serious burns can result.

Abbott Laboratories, Inc., Product Information: Similac® Special Care® 24 High Protein, WWW.ABBOTTNUTRITION.COM, https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Similac®-Special-Care-24-High-Protein.pdf (last visited Apr. 14, 2022).

113. Defendant provides the following warnings for its product Similac® Special Care® 30 formula:

Safety Precautions

Very-low-birthweight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously.

Use this product only after feedings of lower caloric density are well-established. For improved tolerance, it is best to increase caloric density slowly, by 2- to 4-Cal/fl oz increments.

Hydration status should be monitored.

Spitting up, abdominal distension, abnormal stools or stool patterns, excessive gastric residuals, or other signs of intestinal dysfunction have been associated with enteral feeding before the intestinal tract is ready to accommodate the regimen. At first signs of these problems, enteral feeding should be slowed or discontinued.

Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb) or as directed by a physician.

Never use a microwave oven to warm formula. Serious burns can result.

Abbott Laboratories, Inc., Product Information: Similac® Special Care® 30, WWW.ABBOTTNUTRITION.COM, https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Similac-Special-Care-30.pdf (last visited Apr. 14, 2022).

114. Defendant provides the following warnings for its Human Milk Fortifier (powder form):

Safety Precautions

Add only to human milk - do not add water.

Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk.

Once enteral feeding is well established, Similac Human Milk Fortifier Powder can be added to human milk.

> Powdered infant formulas are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor.
>
> **Never use a microwave oven to warm feedings**. Serious burns can result.

Abbott Laboratories, Inc., Product Information: Similac® Human Milk Fortifier Powder, WWW.ABBOTTNUTRITION.COM, https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Similac-Human-Milk-Fortifier-Powder.pdf (last visited Apr. 14, 2022).

115. Defendant provides the following warnings for its Human Milk Fortifier (concentrated-liquid form):

> Safety Precautions
>
> Add only to human milk - do not add water.
>
> This product is nutritionally incomplete by itself and is designed to be added to human breast milk.
>
> Additional iron may be necessary.
>
> Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk.
>
> Once enteral feeding is well established, Similac Human Milk Fortifier Concentrated Liquid can be added to human milk.
>
> **Never use a microwave oven to warm feedings**. Serious burns can result.

Abbott Laboratories, Inc., Product Information: Similac® Human Milk Fortifier Concentrated Liquid, WWW.ABBOTTNUTRITION.COM, https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Similac-Human-Milk-Fortifier-Concentrated-Liquid.pdf (last visited Apr. 14, 2022).

116. Defendant provides the following warnings for its product Liquid Protein Fortifier:

> Safety Precautions
>
> If signs of intolerance develop, slow feeding or discontinue.
>
> This product is nutritionally incomplete.
>
> Must be mixed with human milk, fortified human milk, or formula before feeding.
>
> Enteral use only; not for IV use.

Abbott Laboratories, Inc., Product Information: Similac® Special Care® 30, WWW.ABBOTTNUTRITION.COM, Abbott Laboratories, Inc., Product Information: Liquid Protein Fortifier, WWW.ABBOTTNUTRITION.COM, https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/Liquid-Protein-Fortifier.pdf (last visited Apr. 14, 2022).

117. None of the "Safety Precautions" Defendant provided with the Products warned of the risk of NEC.

118. Despite knowing that cow's-milk-based products significantly increase premature infants' risk of NEC, surgery, and/or death, Defendant did not warn consumers of these risks or the magnitude by which cow's-milk-based products increased these risks.

119. Defendant likewise did not provide instructions or guidance for how to feed these products to attempt to avoid or mitigate these risks.

120. Although Defendant's products are sometimes given to infants at medical facilities, all of the Products except the Abbott Nutrition Liquid Protein Fortifier are marked to the public and available for consumers to purchase without a doctor's

prescription. The Liquid Protein Fortifier is sold directly to medical facilities, but like the direct-to-consumer Products, it lacks any warning about NEC. Indeed, Defendant's products, including the Products, are often donated to medical facilities so that parents will develop brand loyalty and purchase the same brand of products post-discharge.

121. Defendant deceived the public, parents, physicians, other medical professionals, and medical staff into believing that is the Products are a safe and necessary alternative, supplement, or substitute to breast milk for premature infants.

122. Despite knowing that cow's-milk-based products were being fed to preterm infants as marketed, often without the parents' informed consent, Defendant failed to require or recommend that medical professionals or hospitals inform parents of the significant risk of NEC, surgery, or death.

123. Despite knowing that its cow's-milk-based products, including the Products, were being fed to preterm infants as marketed and labeled, often without the parents' informed consent, Defendant failed to require or recommend that medical professionals obtain the parents' informed consent before feeding these cow's-milk-based products to premature infants.

124. No parent would reasonably expect that an infant formula could be extremely dangerous to their baby unless properly warned and informed of the extreme dangers and risk of NEC, serious injury, surgery, or death.

125. To this day, Defendant has never warned the public about the extreme danger the Products pose for premature infants like Baby Kennedy.

126. Members of the medical community, physicians, and hospitals, as well as the parents, relief upon the representations and advertising of Defendant, which categorically omit that cow's-milk-based products significantly increase the risk of NEC, surgery, and death in premature infants, which contributed to the product being fed to Baby Kennedy.

127. On information and belief, the product label for the Similac® formulas and human-milk fortifier given to Baby Kennedy did not warn consumers or medical professionals about the risk of NEC from giving premature infants cow's-milk-based formulas.

128. Neither the hospital nor the physicians involved in Baby Kennedy's care informed her parents that Defendant's cow's-milk-based products would significantly increase the risk of NEC.

129. Neither the hospital nor the physicians provided a choice to the parents about whether to feed their premature infant cow's-milk-based fortifier or formula. Baby Kennedy spent her entire short life in the NICU, where she was fed by NICU staff. Her parents had to rely on these hospital staff members to feed their child.

130. The Products were not safe to be fed to premature infants like Baby Kennedy. Defendant knew or should have known they were unsafe but failed to provide any instructions or guidelines on whether, when, and how cow's-milk-based formulas would be safe to feed to a premature infant like Baby Kennedy.

131. Science and research have unequivocally established the dangers of Defendant's cow's-milk-based products in causing NEC and death in premature

infants, yet Defendant did nothing to change its products, packaging, guidelines, instructions, and warnings.

132. Defendant knew or should have known that the Products would be used as they were used on Baby Kennedy.

133. The way the Products were fed to Baby Kennedy was extremely dangerous and caused an unreasonably high risk that the baby would develop NEC and die, yet Defendant provided no detailed instructions or warnings to prevent or alter the way this product was used.

134. Despite learning that its products were linked to NEC and death, Defendant failed to properly collect data from patients, parents, doctors, and hospitals to develop evidence-based strategies, instructions, and warnings to reduce or prevent its products from causing NEC and death.

135. On information and belief, despite knowing that its products were leading to NEC and death, Defendant took no steps to determine how or why the products were causing NEC or death.

136. On information and belief, Defendant has learned that its cow's-milk-based products were causing NEC and death in premature infants, yet did nothing to change its products, packaging, guidelines, instructions, and warnings.

137. On information and belief, despite knowing that its products were causing NEC and death in premature infants, Defendant did not contact the FDA, NICUs, hospitals, and/or inform them that its products were linked to causing NEC and death.

138. On information and belief, Baby Kennedy's parents, physicians, and medical staff were never told that Defendant's products would cause the baby to develop NEC.

139. On information and belief, Baby Kennedy's parents, physicians, and medical staff were never told of the studies showing that cow's-milk-based formulas and fortifiers were extremely dangerous for the baby.

140. On information and belief, Baby Kennedy's parents, physicians, and medical staff were never told of the studies showing that safer alternatives to cow's-milk-based formulas existed, including human donor milk and formulas or fortifiers derived from human milk.

141. On information and belief, Baby Kennedy's parents, physicians, and medical staff were never told that an exclusive human-milk diet is sufficient to meet all growth and nutritional goals.

142. On information and belief, despite knowing that its cow's-milk-based products were causing NEC and death in premature infants, Defendant did not recommend or require hospitals, NICUs, or physicians to discuss the risks of NEC or death with the parents.

143. On information and belief, despite knowing that its cow's-milk-based products were causing NEC and death in premature infants, Defendant did not contact the FDA, NICUs, hospitals, and physicians to inform them that Defendant's cow's-milk-based formula was linked to causing NEC and death.

144. This practice of not disclosing the risks of feeding cow's-milk-based fortifier or formula is the common practice throughout the country, including in New Jersey.

Defendant is aware of this practice and is aware that parents are rarely, if ever, informed.

145. Defendant has known for many years that its premature infant products are significantly increasing the risk of premature infants developing NEC and dying and are aware that hospitals and physicians in the United States are not informing parents of preemies of the risk of NEC developing when fed Defendant's products.

146. Defendant knows that if it required or even requested that hospitals and doctors obtain informed consent regarding the risks of feeding Defendant's products to premature infants, the parents would not allow the Defendant's products to be fed to their children.

147. Defendant knows that if its product labels advised that the products should not be fed to premature infants until the parents are warned and informed that feeding the products would significantly increase the risk of NEC or death, then the use of Defendant's products would immediately plummet in hospitals across the country. If the truth and the science were finally brought to light, parents would not allow the products to be fed to their premature infants and Defendant's corporate image would be damaged and its profits diminished.

148. If the hospital or physicians had informed either parent, or if Defendant had required or even requested that the hospitals or physicians inform parents that Defendant's products for premature infants would significantly increase the risk of NEC or death to their infants, Baby Kennedy's parents would not have allowed the

cow's-milk-based products to be fed to her, and she would not have suffered NEC and died.

149. Defendant provides free or discounted products to hospitals, which encourages the products to be overused with no warnings, instructions, or consents.

150. For decades, Defendant has known that there is a complete lack of communication between physicians and parents when it comes to the feeding of Defendant's products to preterm infants. Defendant has done nothing to fix this dangerous practice of silence. The effect of this practice is that premature infants have been needlessly succumbing to NEC and dying after being fed Defendant's products and the parents have no idea why.

151. Baby Kennedy's parents, like most parents whose children suffered from NEC after being fed cow's-milk-based fortifiers or formulas, were never informed why their child developed NEC, and the hospital and its staff never advised the parents of the probable cause being Defendant's products. Despite many years of premature infants developing NEC or dying after being fed Defendant's products, parents remain completely in the dark as to the cause of their child's injury or loss and are not told of the abundance of data linking Defendant's products to NEC and/or death.

The Baby: Baby Kennedy and her exposure to the Products

152. Baby Kennedy was born extremely prematurely with a low birth weight of 712 grams (1 lb. 9 oz.), at 24 weeks and 6 days' gestation.

153. Baby Kennedy was placed in the neonatal intensive care unit at the Morristown Medical Center in Morristown, New Jersey.

154. Baby Kennedy's mother, Nicole Cresap, diligently pumped breastmilk and provided it to be fed to Baby Kennedy.

155. Upon her admission to the NICU, Baby Kennedy was initially fed via total parenteral nutrition. The NICU staff began initiating enteral feeds on her first day of life and advanced to full-volume enteral feeds by her tenth day of life.

156. On January 23, 2022, Baby Kennedy's 23rd day of life, NICU staff placed her on total parenteral nutrition until February 3, 2022.

157. During the times Baby Kennedy was offered enteral nutrition until February 21, 2022, the NICU staff fed her breast milk (whether Ms. Cresap's expressed milk or donor milk) with the "additive" Similac® Human Milk Fortifier. Some of these enteral feedings included both Similac® Human Milk Fortifier and Abbott Nutrition Liquid Protein Fortifier as "additives" to the human milk.

158. On February 21, 2022, NICU staff "transitioned" Baby Kennedy to formula, including Similac® Special Care® 24 High Protein and Similac® Special Care® 30 High Protein.

159. On March 14, 2022, Baby Kennedy suffered an acute abdominal crisis caused by necrotizing enterocolitis, resulting in complete surgical removal of her intestines from her abdominal cavity, which were placed in a silo, and multi-system organ failure, cardiac arrest, and Baby Kennedy's death. Ms. Cresap witnessed these horrific events.

160. Baby Kennedy's caregivers, including Nicole Cresap, had no knowledge that Similac® formulas and fortifiers would increase Kennedy's risk of developing NEC.

161. Ms. Cresap and Baby Kennedy's father had been exposed to Defendant's advertisements for years.

162. Based on Defendant's marketing of its formulas and fortifiers, including Defendant's marketing of the Products as specifically intended to address premature infants' needs, Baby Kennedy's parents believed the Products were not only safe for Baby Kennedy to consume but necessary for her growth and nutrition as a premature infant.

163. Although Defendant aggressively markets its products, including the Products, to make parents believe Defendant's products are safe and necessary for growth of a premature infant, the product is in fact extremely dangerous for premature infants. Defendant's cow's-milk-based products, including the Products, substantially increase the chances of a premature infant getting NEC and dying.

164. The Products are commercially available at retail locations and online. No prescription is necessary.

165. Despite knowing the Products significantly increased the risk of NEC, Defendant did not warn parents of the risk of NEC or death associated with the Products when fed to premature infants.

166. Despite knowing the Products significantly increased the risk of NEC, Defendant did not warn doctors, hospitals, nurses, or other medical staff of the risk of NEC or death associated with the Products when fed to premature infants.

167. Defendant's cow's-milk-based formula and fortifier products, including the Products, are dangerous to premature infants in that they significantly increase the risk that a baby will develop NEC.

168. Defendant's cow's-milk-based formula and fortifier products, including the Products, are dangerous to premature infants in that they significantly increase the risk that a baby will require surgery.

169. Defendant's cow's-milk-based formula and fortifier products, including the Products, are dangerous to premature infants in that they significantly increase the risk that a baby will die.

170. Defendant failed to properly warn parents and medical providers that cow's-milk-based formula and fortifier products, including the Products, can significantly increase the risk that the premature infant will develop NEC, require surgery, and/or die, failed to design products to make them safe, and deceived the public, parents, physicians, and medical staff into believing that the products were a safe and necessary alternative and/or supplement to and/or substitute for human milk.

171. Despite knowing that cow's-milk-based formula and fortifier products, including the Products, were being fed to premature infants without the parents' informed consent, Defendant failed to require or recommend that hospitals inform the parents of the significant risks, and to require parental consent before feeding Defendant's cow's-milk-based products to babies.

172. Defendant's cow's-milk-based formula and fortifier products—specifically, the Products—caused Baby Kennedy to develop NEC, which triggered severe intestinal

disease, the need for serious surgery, excruciating pain, and ultimately caused Baby Kennedy's death.

Safer Alternative Designs

173. Infant formulas and fortifiers made or derived from cow's-milk ingredients, including the Products fed to Baby Kennedy, are unsafe for premature infants and are avoidable because safe alternatives—including human donor milk and human-milk-derived products—are available.

174. Defendant's formulas are not unavoidably unsafe products. For decades before Baby Kennedy was fed the Products, Defendant and the formula industry knew that infant formulas and fortifiers designed and formulated without cow's-milk products were not only scientifically possible but practically feasible. These alternative designs include products derived exclusively from human milk or amino acids without diminishing the product's utility, safety, or effectiveness.

175. Since 2006, Prolacta Bioscience has manufactured and sold fortifiers and formulas for premature infants that contain no cow's-milk products. These products are an example of a feasible alternative design. These alternative designs provide all the necessary nutrition and growth that bovine formula provides, without the deadly effects of NEC.

176. Elemental formulas present another feasible alternative design. Elemental, or amino-acid-based formulas, are widely available and are fed to infants after NEC surgery to re-establish enteral feeding because they are more easily digested than traditional formulas.

177. In fact, Defendant has manufactured and sold elemental amino-acid-based formulas that do not contain cow's-milk ingredients under the brand name EleCare® since 1998. https://elecare.com/?psproductGroup=US%20Elecare&sku=US_55251 (last accessed Mar. 28, 2022).

178. SHS International, Ltd. manufactures and sells elemental amino-acid-based formulas that do not contain cow's-milk ingredients under the brand name Nutricia® Neocate®. https://www.neocate.com/shop/hypoallergenic-formula-and-products/infant-dha-ara (last accessed Mar. 28, 2022). This specifically includes Nutricia® Neocate® Syneo® infant formula, which SHS International, Ltd. has sold since 2016. https://www.neocate.com/syneo/ (last accessed Apr. 11, 2022).

179. Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, makers of Enfamil® infant formulas, have manufactured and sold PurAmino® Hypoallergenic Infant Formula, which the PurAmino® website touts as "a hypoallergenic, iron fortified, amino acid-based infant formula used for infants and toddlers with severe cow's milk protein allergy, and other food allergies" since 2013. PurAmino® is an elemental amino-acid-based formula. https://www.enfamil.com/products/puramino-formula/ (last accessed Mar. 28, 2022).

180. Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, also began manufacturing and selling Nutramigen, a cow's-milk-free elemental formula marketed as "the first infant formula for the nutritional management of cow's milk allergy" in ***1942***. https://www.nutramigen.co.uk/why-nutramigen/history-of-mead-johnson-nutrition/ (last accessed Mar. 28, 2022)

181. At a minimum, Defendant should have conducted research and investigation into whether elemental formulas, alone or in combination with human milk sources or parenteral feeding, could have been used to establish enteral feeding in premature infants before introducing or reintroducing a cow's-milk-based formula with hydrolyzed or intact cow's-milk-based proteins.

182. The use of elemental formulas to re-establish enteral feeding in infants who have had their intestines resected during NEC surgery indicates that elemental formulas would, at a minimum, be safe for premature infants to consume to establish enteral feeding initially before introducing other formula products.

183. On information and belief, Defendant was aware of the increased risk of NEC and death associated with their cow's-milk-based products and instead of warning of the dangers or removing them, Defendant has stubbornly insisted on continuing to use cow's milk as the foundation of the Products, which are marketed to and labeled for feeding to premature infants.

184. Defendant is aware of the increased risk of NEC associated with the use of cow's-milk-based products as opposed to human milk. As a result, Defendant has attempted to remedy its inherently defective Similac® product line by researching and developing products that mimic human milk by (1) creating probiotics that are similar to human milk; (2) developing human milk oligosaccharides that are found in human milk; and (3) attempting to hydrolyze cow's-milk proteins to make them easier to digest and resist infection. Despite these developments, Defendant has continued

to market and produce cow's-milk-based products for premature infants without any instructions or warnings to reduce the risk of NEC.

COUNT 1: PRODUCTS LIABILITY—DEFECTIVE DESIGN

185. Plaintiff incorporates all prior allegations.

186. Defendant is liable to Plaintiff under the New Jersey Products Liability Act, N.J. Stat. § 2A:58C-1, *et seq*., because the Products, which proximately caused Baby Kennedy to develop NEC and die, were not reasonably fit, suitable, or safe for their intended purpose because they were designed in a defective manner.

187. Before Baby Kennedy's birth on December 30, 2021, Defendant was or should have been aware that its cow's-milk-based formula and fortifier products, including the Products, were not safe for use in premature infants because formulas and fortifiers based on or derived from cow's milk significantly increase the risks of NEC when fed to premature infants.

188. Defendant's design for its premature-infant formulas and fortifiers, including the Products, was defective because it included ingredients known to cause NEC in premature infants.

189. Cow's-milk ingredients are not necessary components of infant formula or fortifier, so they are not an unavoidably unsafe aspect of the product.

190. Before December 30, 2021, there existed one or more practically and technically feasible alternatives to designing or formulating infant formula and fortifiers without using cow's milk that would have prevented the harm without impairing the reasonably anticipated or intended function of the Products. These

feasible design alternatives included formulas and fortifiers based on or derived from human milk or amino acids.

191. Cow's-milk ingredients can be eliminated from infant formulas and fortifiers without substantially compromising the products' usefulness or desirability. To the contrary: human-milk-based or amino-acid-based formulas and fortifiers would be more useful and desirable to consumers.

192. Ordinary consumers, including parents of premature infants, did not and do not know that Defendant's cow's-milk-based formula and fortifier products, including the Products, can cause NEC.

193. The Products were not accompanied by an adequate warning or instruction to apprise users of the risk of NEC.

194. Defendant expressly marketed and labeled the Products fed to Baby Kennedy as safe, suitable, and necessary for premature infants. Thus, Defendant foresaw or should have foreseen that the Products would be fed to premature infants, which would significantly increase these infants' risk of NEC, surgical treatment, and death.

195. Despite knowing that its cow's-milk-based formula and fortifier products, including the Products, were causing NEC in premature infants, Defendant did not conduct any testing, data analysis, or research to determine when its products should not be used, when and how its products were safe for use, and whether it should implement an alternative design for premature-infant formulas.

196. Defendant has known that its cow's-milk-based formula and fortifier products, including the Products, significantly increase the risk of NEC, the need for surgery, and/or death in premature infants and have known that there are feasible alternative designs to cow's-milk-based fortifiers and formulas that would reduce the risk of NEC and death. But Defendant chose to continue to promote, market, and sell cow's-milk-based products, causing thousands of premature infants to develop NEC, require surgery, and/or die.

197. Defendant's defectively designed premature-infant formulas and formulas proximately caused Baby Kennedy to develop NEC, require surgery, and die.

198. To a reasonable probability, Baby Kennedy would not have developed NEC, required the surgery removing her intestines, experienced multi-system-organ failure, and died if she had received a human-milk-only diet.

199. By failing to implement an alternative design for its premature-infant formulas and fortifiers despite knowledge of the danger cow's-milk-based products pose to premature infants, Defendant acted with actual malice and/or a willful and wanton disregard for the safety of these infants.

200. Defendant is thus liable to Plaintiff under the New Jersey Products Liability Act for manufacturing, aggressively marketing, and selling cow's-milk-based formulas for feeding to premature infants because the formulas were defective in design.

201. Given the reprehensibility of Defendant's conduct, which was undertaken with actual malice and/or wanton and willful disregard for the safety of the vulnerable

infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under the New Jersey Punitive Damages Act, N.J. Stat. § 2A-15-5.9, *et seq*.

202. Defendant has failed to take corrective action after learning about how its cow's-milk-based formula and fortifier products, including the Products, have caused infants to NEC, surgical treatment, and death. Instead, Defendant has actively concealed information about how its products cause NEC from the public and profited substantially from these actions.

203. Punitive damages are necessary to punish Defendant and deter Defendant and other massive infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based formulas for feeding to premature infants.

COUNT 2: PRODUCTS LIABILITY—FAILURE TO PROVIDE ADEQUATE WARNINGS AND INSTRUCTIONS

204. Plaintiff incorporates all prior allegations.

205. Defendant is liable to Plaintiff under the New Jersey Products Liability Act, N.J. Stat. § 2A:58C-1, *et seq*., because the Products, which caused Baby Kennedy to develop NEC and die, were not reasonably fit, suitable, or safe for their intended purpose because Defendant failed to provide adequate warnings or instructions with the Products.

206. Defendant manufactured and sold the Products.

207. Defendant's cow's-milk-based formula and fortifier products, including the Products, are not prescription drugs, medical devices, or other products intended to be used only under the supervision of a physician or other medical professional.

208. Defendant sold the Products to hospitals and directly to consumers.

209. Consumers can purchase and use three of the four Products (Similac® Special Care® 24 High Protein, Similac® Special Care® 30, and Similac® Human Milk Fortifier) without a prescription, letter of medical necessity, or medical provider's guidance. Hospitals can purchase and use the fourth product, Abbott Nutrition Liquid Protein Fortifier.

210. At the time the Products left Defendant's control, Defendant knew or, in light of reasonably available knowledge should have known, that cow's-milk-based formulas and fortifiers caused NEC in premature infants and that the ordinary consumers of these formulas (caregivers for premature newborns) would not realize the Products' dangerous condition.

211. The significantly increased risk of NEC was not an open and obvious danger of the Products, which were labeled for feeding to premature infants.

212. Despite Defendant's knowledge of this dangerous condition and consumers' lack of awareness of the danger, Defendant failed to provide an adequate product warning or instruction that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger. A reasonably prudent person would consider NEC to be a serious risk and warn that the Product could cause NEC in premature infants.

213. Defendant further failed to provide an adequate warning or instruction that took into account the characteristics of, and ordinary knowledge common to, the persons by whom the product is intended to be used. It was not, and is not, common

knowledge among ordinary parents of premature newborns that Defendant's cow's-milk-based formulas and fortifiers can cause NEC in premature infants.

214. Defendant's products, including the Products, did not contain a warning label approved by the Food and Drug Administration under 21 U.S.C. § 301, *et seq*., so Defendant is not entitled to a rebuttable presumption that its warning label was adequate.

215. Defendant knew or should have known that its cow's-milk-based formula and fortifier products, including the Products, would be fed to extremely premature and extremely low-birth-weight infants like Baby Kennedy, but Defendant failed to properly warn hospitals, NICUs, doctors, parents, and/or consumers that Defendant's cow's-milk-based products significantly increase the risk of NEC and death in those babies.

216. Defendant is thus liable to Plaintiff under the New Jersey Products Liability Act for failing to warn in all of the following specific ways:

a. Defendant failed to provide any warning or instruction to consumers that its cow's-milk-based formula and fortifier products, including the Products, increased the risk of NEC for extremely premature infants and low-birth-weight babies like Baby Kennedy;

b. Defendant failed to have a large and prominent black-box-type warning that its cow's-milk-based formula and fortifier products, including the Products, are known to significantly increase the risk of NEC, surgery, and/or death for premature infants when compared to human milk;

c. Defendant failed to provide instructions that parents, physicians, NICU staff, and hospital administrators needed to make an informed choice between the safety of human milk versus the dangers of Defendant's cow's-milk-based products;

d. Defendant failed to provide proper instructions, guidelines, studies, or data on when and how to feed Defendant's products to premature infants to decrease the risk of NEC;

e. Defendant failed to provide any warning or instruction to medical professionals (including nurses, physicians, and other healthcare providers) and hospital administrators that its cow's-milk-based formula and fortifier products, including the Products, increased the risk of NEC for extremely premature infants and low-birth-weight babies like Baby Kennedy;

f. Defendant failed to send "Dear Dr." letters warning of the risks of NEC, the need for surgery, and/or death based on the current scientific research and data to better guide hospitals and physicians caring for premature infants;

g. Defendant failed to advise physicians and healthcare providers that cow's-milk-based products are not necessary to achieve growth and nutritional targets for premature infants;

h. Defendant failed to advise physicians and healthcare providers that human milk is superior to cow's-milk-based products to support the nutrition and health of a premature infant;

i. Defendant failed to instruct or warn that an exclusive human-milk-based diet significantly decreases the risk of NEC when compared to a diet that includes cow's-milk-based products;

j. Defendant failed to advise physicians and healthcare providers that human-milk-based products and amino-acid-based formulas were viable alternative to cow's-milk-based products to significantly reduce the risk of premature infants developing NEC;

k. Despite knowing that parents were not being warned of the risk of NEC by their children's physicians, Defendant failed to directly warn the parents of the risk that its cow's-milk-based formulas would cause NEC; and/or

l. Defendant failed to instruct physicians on whether, when, or how to safely transition to cow's-milk-based products;

m. Defendant failed to require or recommend that hospitals and/or physicians inform parents before feeding Defendant's products to their premature babies that cow's-milk-based products significantly increase the risk of NEC, the need for surgery, and/or death;

n. Defendant failed to provide a thorough and detailed risk-benefit analysis on the decision to feed cow's-milk-based formulas to premature infants for hospitals, doctors, and parents;

o. Defendant failed to develop a protocol for hospitals and physicians to ensure safe use of cow's-milk-based formulas;

p. Defendant failed to provide detailed and adequate instructions on proper use, administration, application, and limitations of its products specifically designed for premature infants;

q. Defendant failed to provide periodic or yearly safety reports;

r. Defendant failed to provide periodic or yearly risk-benefit analyses for use of its products;

s. Defendant failed to develop comprehensive mitigation strategies to reduce the risk of NEC, surgery, and death from its products specifically designed and marketed for premature infants;

t. Defendant failed to publish a label or instruction that would correspond to the current science regarding the serious risks associated with using the Products;

u. Defendant failed to provide consumers with statistical evidence of adverse effects regarding the feeding of its products;

v. Defendant failed to guide or instruct medical professionals and infant caregivers regarding when to start feeding an infant cow's-milk-based formulas, how much cow's-milk-based formula to feed premature infants, how to increase volume and timing of feeds, when not to feed premature infants cow's-milk-based formulas, and/or when to stop feeding these products to premature infants;

w. Defendant failed to guide or instruct on how to properly monitor a preterm infant who is fed cow's-milk-based formula and fortifier products, including the Products;

x. Defendant failed to condition the sale or delivery of its products to the hospital with the assurance that hospitals would issue proper warnings about the risk of NEC to the parents;

y. Defendant's warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that Defendant warns and instructs about other specific product uses (including warnings not to microwave formula before feeding it to infants), but does not warn

> that cow's-milk-based formulas and fortifiers significantly increase the risk of NEC, the need for surgery, and/or death for premature infants and provide no information on how to avoid such harm;

217. Defendant's failure to warn was deliberate because Defendant knew that if it advised physicians and healthcare providers of the extreme risks associated with feeding premature infants cow's-milk-based products, they would not have purchased such dangerous products for feeding to premature infants in hospitals, including neonatal intensive care units.

218. Defendant's massive marketing campaign as detailed above has had the effect of: (1) diminishing the ability of parents to intelligently resist the decision of a healthcare provider to feed cow's-milk-based products; (2) diminishing mothers' desire to breastfeed by framing it as a personal decision without health ramifications for infants, especially premature infants; (3) diminishing mothers' confidence in the capability of their bodies to provide sufficient and adequate nutrition for their premature infants without help from Defendant's products; (4) interfering with and supplanting the physician-patient relationship with respect to nutritional decision-making for newborns; (5) making it more difficult for a physician or other medical provider to persuade a mother to breastfeed; and (6) making it easier and more economically viable for hospitals to feed preemies cow's-milk-based product rather than donor milk or human-milk-derived products.

219. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of Defendant's products, Baby Kennedy was fed Defendant's cow's-milk-based formula and fortifier products (the Products), which caused her to develop NEC, require surgery, and die.

220. As a result of Defendant's failures to warn in violation of the New Jersey Products Liability Act detailed above, Baby Kennedy was fed the Products in the NICU, which caused her to develop NEC, require surgery, and die.

221. Given the reprehensibility of Defendant's conduct, which was undertaken with actual malice and/or wanton and willful disregard for the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under the New Jersey Punitive Damages Act, N.J. Stat. § 2A-15-5.9, *et seq*.

222. Defendant has failed to take corrective action after learning about how its cow's-milk-based formula and fortifier products, including the Products, have caused infants to develop NEC, require surgical treatment, and die. Instead, Defendant has actively concealed information about how its products cause NEC from the public and profited substantially from these actions.

223. Punitive damages are necessary to punish Defendant and deter Defendant and other massive infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based products for feeding to premature infants.

COUNT 3: UNFAIR TRADE PRACTICES

224. Plaintiff incorporates all prior allegations.

225. Defendant is liable to Plaintiff under the New Jersey Unfair Trade Practices Act, N.J. Stat. § 56:8-1, *et seq*. because Defendant's marketing of the Product used unconscionable commercial practices, deception, fraud, false pretenses, false promises, misrepresentations, and the knowing concealment, suppression, or

omission of material facts with intent that the public rely upon such concealment, suppression, or omission.

226. The allegations contained in the previous paragraphs set forth specific misrepresentations Defendant has made (or failed to make) to consumers, physicians, and medical personnel through its advertising and promotional materials (some of which are reproduced above). On information and belief, Defendant made such misrepresentations on an ongoing and continuous basis, and specifically relevant here, at various points before Baby Kennedy was fed Defendant's cow's-milk-based products.

227. Defendant's misrepresentations about the Products, upon which Plaintiff and Baby Kennedy's medical providers relied, specifically include the following:

a. Defendant misrepresented to parents, infant caregivers, physicians, and other healthcare providers that its cow's-milk-based formula and fortifier products, including the Products, are safe and beneficial for premature infants when Defendant knew or should have known that its products were unreasonably dangerous and caused NEC, the need for surgery, and death in premature infants.

b. Defendant misrepresented to parents, infant caregivers, physicians, and other healthcare providers that its cow's-milk-based formula and fortifier products, including the Products, were necessary to the growth and nutrition of premature infants, when Defendant knew or should have known that the Products were not necessary to achieve adequate growth.

c. Defendant misrepresented that its cow's-milk-based formula and fortifier products, including the Products, have no serious health risks or side effects, when Defendant knew or should have known the contrary to be true.

d. Defendant misrepresented that its cow's-milk-based formula and fortifier products, including the Products, are safe for premature infants.

e. Defendant misrepresented that cow's-milk-based formula and fortifier products, including the Products, are necessary for premature infants to achieve optimum growth.

f. Defendant negligently misrepresented that cow's-milk-based products are similar or equivalent to human milk for premature infants.

g. Defendant negligently misrepresented that cow's-milk-based products are superior to human milk for feeding premature infants because the products are created by "science."

h. Defendant chose to denominate some of its products "Human Milk Fortifier," which misleadingly suggests to average consumers that the products are made from human milk (which they are not) and also suggests that human milk is nutritionally deficient, thus requiring "fortification."

228. Defendant's misrepresentations were a proximate cause of Baby Kennedy developing NEC, requiring surgery, and dying.

229. Defendant, at all relevant times, knew or should have known—based on existing studies—that formula marketing negatively impacts a mother's decision to lactate and produce her own milk but nonetheless aggressively marketed formulas for premature infants.

230. Despite ample evidence that its cow's-milk-based formula and fortifier products, including the Products, cause NEC, the need for surgery, and death in premature infants, Defendant has marketed its products as safe for premature infants.

231. Despite ample evidence that its cow's-milk-based products are not necessary for the adequate growth of premature infants, Defendant has marketed their products to parents as necessary for "catchup growth" in premature infants.

232. Despite ample evidence that exclusive human-milk nutrition is sufficient on its own to help premature infants grow, Defendant has marketed its cow's-milk-based products to parents, physicians, and healthcare providers as necessary for "catchup growth" in premature infants.

233. Despite ample evidence that its cow's-milk-based products caused premature infants' intestines to literally necrotize and turn black after developing NEC, Defendant has marked its products as so beneficial to babies' gut health that babies' intestines will glow.

234. Baby Kennedy's mother, Ms. Cresap, was exposed to the kind of deceptive marketing described above portraying cow's-milk-based products (including the Products) as a safe and reasonable alternative to breast milk and necessary for "catch-up growth" in premature infants.

235. As a result of the false representations described above, Baby Kennedy's mother was led to believe that cow's-milk-based formula and fortifiers were safe and suitable alternatives or supplements to breast milk for feeding premature infants.

236. Given the reprehensibility of Defendant's conduct, which was undertaken with actual malice and/or wanton and willful disregard for the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under the New Jersey Punitive Damages Act, N.J. Stat. § 2A-15-5.9, *et seq*.

237. Defendant has failed to take corrective action after learning about how its cow's-milk-based formula and fortifier products, including the Products, have caused

infants to develop NEC, require surgical treatment, and die. Instead, Defendant has actively concealed information about how its products cause NEC from the public and profited substantially from these actions.

238. Punitive damages are necessary to punish Defendant and deter Defendant and other massive infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based formulas for feeding to premature infants.

239. Because Defendant's unfair trade practices caused Plaintiff to suffer damages, Defendant is liable to Plaintiff for treble damages, attorneys' fees, filing fees, and costs of suit under N.J. Stat. § 56:9-12.

COUNT 4: WRONGFUL DEATH

240. Plaintiff incorporates all prior allegations.

241. Defendant is liable to Plaintiff under the New Jersey Wrongful Death Act, N.J. Stat. § 2A:31-1, *et seq*., because Defendant's wrongful acts caused Baby Kennedy to develop NEC, require surgery, and die.

242. Baby Kennedy experienced unimaginable pre-death pain and suffering.

243. Plaintiff incurred medical expenses for Baby Kennedy's medical treatment.

244. Plaintiff has suffered and will continue to suffer pecuniary loss from the loss of Baby Kennedy's society and companionship for the remainder of Plaintiff's life, including lost financial support, advice, counsel, companionship, and other services that a child would customarily provide to a parent.

245. Under the New Jersey Wrongful Death Act, Plaintiff, as Baby Kennedy's surviving mother and next of kin, should be awarded damages for her economic

losses, including for medical expenses and loss of society, companionship, and support.

COUNT 5: SURVIVAL

246. Plaintiff incorporates all prior allegations.

247. Defendant is liable to Plaintiff under the New Jersey Survival Act, N.J. Stat. § 2A:31-1, *et seq*., because Defendant's wrongful acts caused Baby Kennedy to develop NEC, require surgery, and die.

248. Baby Kennedy experienced unimaginable pre-death pain and suffering because of Defendant's actions and omissions and would have had causes of action against Defendant if she had lived.

249. Baby Kennedy's death required Plaintiff to incur funeral and burial expenses.

250. Under the New Jersey Survival Act, Plaintiff, as Baby Kennedy's estate administrator, should be awarded damages for Kennedy's pre-death pain and suffering and funeral and burial expenses.

251. Given the reprehensibility of Defendant's conduct, which was undertaken with actual malice and/or wanton and willful disregard for the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under the New Jersey Punitive Damages Act, N.J. Stat. § 2A-15-5.9, *et seq*.

252. Defendant has failed to take corrective action after learning about how its cow's-milk-based formula and fortifier products, including the Products, have caused infants to develop NEC, require surgical treatment, and die. Instead, Defendant has

actively concealed information about how its products cause NEC from the public and profited substantially from these actions.

253. Punitive damages are necessary to punish Defendant and deter Defendant and other massive infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based formulas for feeding to premature infants.

COUNT 6: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

254. Plaintiff incorporates all prior allegations.

255. Defendant is liable to Plaintiff for negligently inflicting severe emotional distress by forcing Plaintiff to witness her child's injuries, medical treatment, and death, all of which were shocking and disturbing.

256. Defendant caused Baby Kennedy to die by manufacturing, marketing, and selling its cow's-milk-based formula and fortifier products, including the Products, all of which carry the risk of NEC, surgery, and death, without providing any warning or instruction regarding the risks.

257. Plaintiff shared a close familial relationship with her daughter, Baby Kennedy.

258. Plaintiff observed Baby Kennedy's injuries, pain, suffering, and eventual death, all of which were shocking to Plaintiff, who had no reason to expect that her child would suddenly develop NEC, require an extensive surgery that would result in her intestines being siloed outside her body, and die.

259. Plaintiff has suffered severe emotional distress as a result of observing her infant daughter Baby Kennedy's injuries, including after her NEC surgery, and Baby Kennedy's death.

260. Given the reprehensibility of Defendant's conduct, which was undertaken with actual malice and/or wanton and willful disregard for the safety of the vulnerable infant population who would foreseeably be harmed by Defendant's acts and omissions, the Court should assess Defendant with punitive damages under the New Jersey Punitive Damages Act, N.J. Stat. § 2A-15-5.9, *et seq*.

261. Defendant has failed to take corrective action after learning about how its cow's-milk-based formula and fortifier products, including the Products, have caused infants to develop NEC, require surgical treatment, and die. Instead, Defendant has actively concealed information about how its products cause NEC from the public and profited substantially from these actions.

262. Punitive damages are necessary to punish Defendant and deter Defendant and other massive infant-formula corporations from continuing to manufacture, market, and sell cow's-milk-based formulas for feeding to premature infants.

PRAYER FOR RELIEF

Plaintiff respectfully demands:

1. Entry of judgment in Plaintiff's favor on all claims for relief;
2. Economic and non-economic damages to compensate for the losses suffered;
3. Attorneys' fees and costs of suit;
4. Punitive damages; and
5. Such other relief as the Court deems just and proper.

JURY DEMAND

Plaintiff respectfully demands a jury trial in this matter.

Respectfully submitted,

/s/ Ashlie Case Sletvold

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